



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|------------------------------|------------------|
| 10/686,491 | 10/14/2003 | Rossella G. Tupler | 07917-180001 / UMMC 03-18 | 3543 |
| 26161 | 7590 | 10/31/2007 | EXAMINER | |
| FISH & RICHARDSON PC | | | STANDLEY, STEVEN H | |
| P.O. BOX 1022 | | | ART UNIT | |
| MINNEAPOLIS, MN 55440-1022 | | | PAPER NUMBER | |
| | | | 1649 | |
| | | | MAIL DATE | |
| | | | DELIVERY MODE | |
| | | | 10/31/2007 | |
| | | | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/686,491

Applicant(s)

TUPLER ET AL.

Examiner

Steven H. Standley

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,10,11,21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-7, 21 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 8/15/07 has been made of record. T

Claims 1-2, 5-7, 21, and 23 are under consideration. Claims 10-11 are withdrawn.

Information Disclosure Statement

2. The IDS submitted 8/15/07 has been considered by the examiner. It is noted that the paper cited renders the invention obvious, but it is not by another inventorship and it is less than one year prior to Applicant's filing date.

Objections/Rejections: Withdrawn

Election Restriction

3. Since the examiner has acted on claims that reasonably constituted Group II or the restriction of 10/13/06, the examiner withdraws the requirement for restriction between groups I and II of the restriction of 10/13/06.

Sequence Rules

4. Objection to the specification for failing to comply with sequence rules is withdrawn due to applicant's argument.

Specification

5. Objection to the specification is withdrawn due to applicant's prior amendment and current argument.

Claim Rejections - 35 USC § 102

6. Rejection of claims 1-2 and 7 under 35 USC § 102(b) is withdrawn due to applicant's amendment.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Rejection of claims 1-2, 5-7, 21 and 23 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office action dated 3/22/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the sequence was well-known in the art at the time of filing. This is not found persuasive because, as the examiner argued in the prior office action, the definition relied upon in the specification lacks any structure and is circular. Moreover, whatever constitutes a D4Z4 is highly polymorphic and varies with individual and with species and thus lacks any structure or structural boundaries. As applicants and the art have described it, one would not necessarily recognize a specific DNA sequence as a

Art Unit: 1649

D4Z4 binding element. In summary, one skilled in the art would not recognize the boundaries of what applicant is claiming.

With regard to a generic "4q35 gene," Applicant's arguments and amendments are persuasive.

What constitutes a D4Z4 binding element or a 4q35 D4Z4 binding element appears to the Examiner to be the remaining issue. Also, the number of repeats remains open such that an infinite number of undescribed repeats are encompassed.

8. Rejection of claims 1-2, 5-7, 21 and 23 under 35 USC § 112, 1st paragraph, written description is maintained for the reasons made of record in the office action dated 3/22/07. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that amendment to "a D4Z4 binding element comprising DNA comprising one or more 4q35 d4z4 repeats" obviates the rejection. This is not found persuasive because one of skill in the art would not recognize a 4q35 d4z4 repeat since d4z4 repeats are highly polymorphic and variable and vary between individuals as well as species as argued in the prior action of 3/22/07. Furthermore, as written the claims encompass an infinite number of DNA repeats, whatever they might be.

Conclusion

No claim is allowed.

Art Unit: 1649

THIS ACTION IS MADE FINAL. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

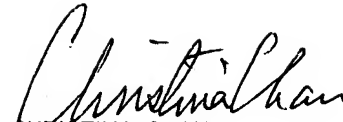
Application/Control Number: 10/686,491

Page 6

Art Unit: 1649

Steve Standley, Ph.D.

10/29/07



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600